

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE  
Group Art Unit 1651

In re

Patent Application of

Thomas H. Barrows, et al.

Application No. 10/810,518

Confirmation No.: 1213

Filed: March 26, 2004

Examiner: Deborah K. Ware

"TISSUE ENGINEERED BIOMIMETIC  
HAIR FOLLICLE GRAFT"

Electronically filed by

Signature

Bally Sorensen

Dec. 28, 2007

Date of Signature

**DECLARATION UNDER 37 CFR § 1.132**

Mail Stop AF  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

I, Thomas H. Barrows hereby declare and state the following:

1. I have personal knowledge of the following facts and I make this declaration in support of the prosecution of U.S. Patent Application Serial No. 10/810,518 before the United States Patent and Trademark Office. I am one of the inventors of the invention described and claimed in the above-noted application.
2. I am currently employed as Technical Director at Aderans Research Institute, a position I have held since 2002. Prior to that I was employed as Vice President of Research & Development at BioAmide, Inc.
3. My *Curriculum Vitae* is attached as Appendix A.

4. I am the inventor of the subject matter of the above-identified application and I am familiar with the art and with the prosecution history of this application.

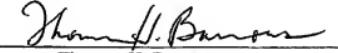
5. I have reviewed the Final Office action dated August 29, 2007, as well as the references cited therein. It is my understanding that the Examiner has rejected claims 32-45 and 48 under 35 U.S.C. § 102(b) as being unpatentable over U.S. Patent Application No. 2003/0049839. It is further my understanding that the Examiner has rejected claims 46 and 47 under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent Application No. 2003/0049839, in view U.S. Patent Application No. 2003/0090725.

6. Tissue engineered skin cells are not recognized in the art as being capable of hair follicle neogenesis. The hair follicle is a complex structure comprising at least ten different cell types. Accordingly, hair follicle neogenesis is a complex process. Naturally occurring cells within the skin, when cultured, are capable of making new skin but are not capable of making new hair.

7. Skin grafts, known as cultured epithelial autografts, may be carried out using cultures containing only epithelial cells.

8. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements and the like so made are punishable by fine or imprisonment or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Dated: 24 - DEC - 2007

  
\_\_\_\_\_  
Thomas H. Barrows

Docket No.: 010414-9012-US00  
Michael Best & Friedrich LLP  
One South Pinckney Street  
PO Box 1806  
Madison, WI 53701-1806  
(608) 257-3501

Attachment: Appendix A

**SUMMARY:** Tissue engineering of human hair follicle-inducing grafts, product development, research management, biomedical materials.

**EXPERIENCE:**

2002-Present [Aderans Research Institute](http://www.aderansresearch.com), Atlanta, GA  
[www.aderansresearch.com](http://www.aderansresearch.com)

**TECHNICAL DIRECTOR**

- Coordinated product development in Atlanta with research in Philadelphia.
- Promoted and supervised development of the pig as an animal model for hair transplant research.
- Recruited a VP of Operations to replace outgoing former BioAmide VP in 2003.
- Supervised the transition of a start-up (BioAmide) to a full-scale research institute.

1999-2002 [BioAmide, Inc.](http://www.bioamide.com), Atlanta, GA

**VICE PRESIDENT, R&D**

- Initiated a project on the development of implants for tissue-engineered hair.
- Set-up a cell culture laboratory at Emtech Biotechnology, Inc. and hired a cell-biologist to perform hair follicle induction research.
- Established a Scientific Advisory Board including experts in dermatologic surgery, pathology, and research.
- Obtained IRB approval and conducted a human clinical investigation.
- Achieved the first documented clinical demonstration of follicle neogenesis and hair grow *via* implantation of cultured cells on a bioabsorbable polymer scaffold (*i.e.* tissue-engineered hair).
- Participated in negotiations leading to acquisition by Aderans in 2002.

1999-2000 [Georgia Tech/Emory Center for the Engineering of Living Tissues](http://www.gtevt.org), Atlanta, GA

**AFFILIATE**

- Collaborated with Prof. Robert Guldberg and graduate student Angela Lin on the development and evaluation of high-strength scaffolds for tissue engineered bone.
- Managed a project on bioabsorbable fiber-reinforced composite pin manufacture and performance testing at Georgia Tech (with Prof. Guldberg and Angela Lin) and the University of Tennessee, Knoxville (with Prof. Spruill and Regina Holmes).

1996-1999 [Focal, Inc.](http://www.focalinc.com), Lexington, MA

**PRINCIPAL SCIENTIST**

- Supervised the Materials Research Team leading to the synthesis, scale-up, pre-clinical, and clinical development of FocalSeal-ST<sup>TM</sup> for use in neurosurgery to prevent cerebrospinal fluid leaks and subsequent infections and meningitis.

- Direct responsibility for supervision of four Ph.D. chemists and two B.S. degree chemists.

1985-1996

Life Sciences Sector Laboratory/3M, St. Paul, MN**SENIOR RESEARCH SPECIALIST**

- Invented and developed a new semi-synthetic tissue sealant for use in lung surgery that was successfully evaluated in pre-clinical and clinical studies for safety and efficacy.
- Perfected and scaled-up monomer and polymer syntheses and purification procedures under GMP at pilot plant facilities in the US and France.

1978-1985

Life Sciences Sector Research Laboratory/3M, St. Paul, MN**RESEARCH SPECIALIST**

- Conducted basic research in the metabolic fate of hydrolyzable polymers using carbon-14 labeled monomers.
- Invented a new class of bioabsorbable poly(ester-amides). Designed specific polymer structures for high performance fiber applications including absorbable sutures and ligament reconstruction implants.
- Identified and developed new product opportunities in the fields of peripheral nerve repair, fracture fixation and bone remodeling, drug delivery, skin stapling, and tissue adhesives.

1974-1978

Central Research Laboratories/3M, St. Paul, MN**SENIOR RESEARCH CHEMIST**

- Synthesized polymers for tissue compatibility, bioabsorbability, tissue adhesive, and drug delivery studies.
- Performed analyses of bioabsorbable fiber performance characteristics using accelerated *in vitro* hydrolysis conditions.
- Conducted research on blown microfiber production of bioabsorbable polymers.

**EDUCATION:**

1974 Ph.D. Organic Chemistry, The Pennsylvania State University, University Park, PA

1969 B.S. Chemistry, University of Georgia, Athens, GA

1965 Sandy Springs High School, Atlanta, GA

**PROFESSIONAL SOCIETIES:**

North American Hair Research Society

Tissue Engineering &amp; Regenerative Medicine International Society (TERMIS)

The Society for Biomaterials  
The American Chemical Society

- HONORS:** Fellow of the American Institute for Medical and Biological Engineering (AIMBE), Class of 1999.  
Various awards bestowed by 3M including: The Circle of Technical Excellence Award, The Genesis Research Grant Award, and the Corporate Challenge '81 Award.
- PATENTS:**
- T.H. Barrows, "Scaffolds for Tissue Engineered Hair", U.S. Patent 7,198,641, April 3, 2007.
- S.A. Cochran, B. Marshall, T.H. Barrows, Y. Su, R. Schlicher, "Hair Follicle Graft Derived from Plucked Hair", U.S. Patent Application Publication US 2007/0122387 May 31, 2007.
- T.H. Barrows, P. McIntyre, K.J. Washenik, "Hair Follicle Graft from Tissue Engineered Skin", U.S. Patent Application Publication US 2007/0148138, June 28, 2007.
- T.H. Barrows, "Filamentary Means for Introducing Agents into the Tissue of a Living Body", U.S. Patent 6,884,427, April 26, 2005.
- T.H. Barrows, "Bioabsorbable Fibers and Reinforced Composites Produced Therefrom", U.S. Patent 6,511,748, January 28, 2003.
- T.H. Barrows, "Device of Bioabsorbable Triglycolic Acid Poly(ester-amide)s, and Methods of Making the Same", U.S. Patent 6,365,172, April 2, 2002.
- T.H. Barrows, "Hair Follicle Neogenesis by Injection of Follicle Progenitor Cells", International Patent WO 02/060396 A2, August 8, 2002.
- T.H. Barrows, "Bioabsorbable Triglycolic Acid Poly(ester-amide)s", U.S. Patent 6,120,788, September 19, 2000.
- T.H. Barrows, M.T. Truong, and P.R. Suszko, "Biocompatible Porous Matrix of Bioabsorbable Material", U.S. Patent 5,856,367, January 5, 1999.
- T.H. Barrows, T.W. Lewis, and M.T. Truong, "Adhesive Sealant Composition", U.S. Patent 5,583,114, December 10, 1996.
- T.H. Barrows, M.T. Truong, and P.R. Suszko, "Biocompatible Porous Matrix of Bioabsorbable Material", U.S. Patent 5,502,092, March 26, 1996.
- T.H. Barrows, M.T. Truong, P.R. Suszko, and D.W. Stegink, "Process for Increasing Stability of Poly (ester-amides)", U.S. Patent 5,286,837, February 15, 1994.
- T.H. Barrows and M.T. Truong, "Bioabsorbable Poly(ester-amides) and method for Making Same", International Patent WO 93/13814, July 22, 1993.
- T.H. Barrows, "Semiabsorbable Bone Plate Spacer", U.S. Patent 5,013,315, May 7, 1991.
- T.H. Barrows, "Absorbable Nerve Repair Device and Method", U.S. Patent 4,883,618, November 28, 1989.
- T.H. Barrows and H.E. Froehlich, "Surgical Staple", U.S. Patent 4,719,917, January 19, 1988.

T.H. Barrows, "Absorbable Nerve Repair Device and Method", U.S. Patent 4,669,474, June 2, 1987.

T.H. Barrows, "Absorbable Sutureless Nerve Repair Device", U.S. Patent 4,534,349, August 13, 1985.

T.H. Barrows, "Process for Preparing Synthetic Absorbable Poly(ester-amides)", U.S. Patent 4,529,792, July 16, 1985.

T.H. Barrows, "Polymeric Acid Contraceptive Devices and Method", U.S. Patent 4,360,013, November 23, 1982.

T.H. Barrows, "Synthetic Absorbable Surgical Devices of Poly(ester-amides)", U.S. Patent 4,343,931, August 10, 1982.

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K. Stenn, S. Parimoo, Y. Zheng, T. Barrows, M. Boucher, and K. Washenik, "Bioengineering the Hair Follicle", *Organogenesis*, 3(1), 2007.

Y. Su, B. Marshall, S. Cochran, R. Lorenz, S. Parimoo, L. Herron, and T. Barrows, "Hair Follicle Neogenesis in the Adult Pig by Implantation of Trichogenic Cells Obtained from Neonatal Pig Skin", *Annual Hilton Head Workshop: Engineering Tissues 2007*, Sea Pines Plantation, Hilton Head, SC, March 7-11, 2007.

Megan Oest, Angela Lin, Thomas Barrows, and Robert Guldberg, "Oriented Porous Poly(L/DL-Lactide) Scaffolds for Bone Regeneration", *Society of Plastics Engineers (ANTEC peer-reviewed technical conference)*, Boston, MA, May 1-5, 2005.

Stephen Cochran, Thomas Barrows, Ying Zheng, John Holbrook, and Kurt Stenn, "Hair Follicle Neogenesis from Dissociated Newborn Mouse Skin Cells Injected into the Nude Mouse", *ET 2005: Engineering Tissues, 9th Annual Hilton Head Workshop*, Sea Pines Plantation, Hilton Head, SC, March 9-13, 2005.

A.S. Lin, T.H. Barrows, S.H. Cartmell, and R.E. Guldberg, "Microarchitectural and mechanical characterization of oriented porous polymer scaffolds", *Biomaterials*, 24(3), 481-9 (2003).

T.H. Barrows, S.A. Cochran, E.I. Griffin, and A.R. Solomon, "Tissue Engineered Human Hair: Preliminary Clinical Results", *TE2002: International Workshop on Tissue Engineering*, St. Gallen, Switzerland, 24-27 February, 2002.

R.N. Holmes, J.E. Spruiell, T.H. Barrows, A.S.P. Lin and R.E. Guldberg, "Core/Sheath Polylactide Fiber-Reinforced Composites", *Trans. Soc. Biomater.*, 24, 27 (2001).

A.S.P. Lin, T.H. Barrows, S.H. Cartmell and R.E. Guldberg, "Manufacture and Characterization of 3D Porous Scaffolds for Bone Tissue Engineering", *Trans. Soc. Biomater.*, 24, 286 (2001).

A. Coury, T. Barrows, *et al.*, "Development of Synthetic Coatings for Textile Vascular Prostheses", *Trans. Sixth World Biomater. Cong.*, 1497, (2000).

B.C. Poff, D. Warnock, S. Barman, J. Rajaratnam, J. Terrazzano, E. Drake, T. Barrows, and A.J. Coury, "Chronic Biocompatibility of a Hydrogel Dural Sealant in the Rat Brain", *Trans. Soc. Biomater.*, 22, 42 (1999).

- A.J. Coury, S.P. Barman, N. Hoffman, T.H. Barrows, and B. Poff, "Development of a Synthetic Absorbable Tissue Sealant: Preclinical Studies", *Proceedings, 4<sup>th</sup> NJ Symposium on Biomaterials and Medical Devices*, Rutgers University, New Brunswick, NJ, Nov., 1997.
- T.H. Barrows, M.T. Truong, T.W. Lewis, D.M. Grussing, K.H. Kato, J.E. Gysbers, and E.G. Lamprecht, "Evaluation of a New Tissue Sealant Material: Serum Albumin Crosslinked *In Vivo* with Polyethylene Glycol" *Trans. Fifth World Biomater. Cong.*, 1,8, (1996).
- M.T. Truong, T.H. Barrows, and T.J. Wilson, "In Vitro Analysis of Mechanical Properties of a New Tissue Sealant Material: Polyethylene Glycol Crosslinked Serum Albumin" *Trans. Fifth World Biomater. Cong.*, 2,73, (1996).
- S. Gogolewski, P. Michel, and T.H. Barrows, "Sterility, Molecular and Mechanical Properties of Heat-Treated Resorbable Poly(Ester-Amides). PEA 10.2 and PEA 10.6", *Trans. Fifth World Biomater. Cong.*, 2, 700, (1996).
- M.T. Truong, T.H. Barrows, H.P. Goldmann, R. Althaus, and K.H. Fullgrabe, "In Vitro Conditions for Accelerated Hydrolysis of Bioabsorbable Fibers", *Trans. Soc. Biomater.*, 18, 436 (1995).
- T.H. Barrows, "Bioabsorbable Poly(ester-amides)", in "Designed to Degrade Biomedical Polymers", S.W. Shalaby, ed., Chapter 4, p. 97-116, Carl Hanser Verlag Publisher, 1994.
- T.H. Barrows, M.T. Truong, P.R. Johnson, and M.A. Havens, "In Vitro Comparison of the Hydrolysis of Polylactic Acid and Poly(ester-amide) Fibers", *Trans. Fourth World Biomater. Congress*, 15, 249 (1992).
- D.F. Gibbons, T.H. Barrows, and M.T. Truong, "Tissue Response to Local High Concentration of Resorbing Polymer", *Trans. Fourth World Biomater. Congress*, 15,408 (1992).
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- V.L. Horton, P.E. Blegen, T.H. Barrows, et al., "Comparison of Bioabsorbable Poly(ester-amide) Monomers and Polymers *In Vivo* using Radiolabeled Homologs", in *Progress in Biomedical Polymers*, C.G. Gebelein and R.L. Dunn. Eds., Plenum Press, New York, p. 263-282, 1990.
- L. Claes, C. Burri, H. Kiefer, T. Barrows, and D. Gibbons, "Resorbable Implants for the Treatment of Bone Defects", *Trans. Third World Biomater. Congress*, 11,499 (1988).
- T.H. Barrows, G.J. Quarforth, P.E. Blegen, and R.L. McQuinn, "Comparison of Bioabsorbable Poly(ester-amide) Monomers and Polymers *In Vivo* using Radiolabeled Homologs", *Poly. Mater. Sci. Eng.*, 59, (1988).
- C.P. Tountas, R.A. Bergman, T.H. Barrows, et al., "Peripheral Nerve Repair: tubulization vs. Suture, a 12 month primate study", American Society for Surgery of the Hand, 42<sup>nd</sup> Annual Meeting, San Antonio, TX, September 1987.
- T.H. Barrows, J.D. Johnson, S.J. Gibson, and D.M. Grussing, "The Design and Synthesis of Bioabsorbable Poly(ester-amides)", in "Polymers in Medicine II", vol. 3, E. Chiellini, ed., Plenum Press, New York, p. 85-90, 1986.
- T.H. Barrows, "Degradable Implant Materials: A Review of Synthetic Absorbable Polymers and their Applications", *Clinical Materials*, 1, 233-257 (1986).

C.P. Tountas, R.A. Bergman, H.V. Mendenhall, and T.H. Barrows, "Peripheral Nerve Repair by Tubulization", American Society for Surgery of the Hand, 41<sup>st</sup> Annual Meeting, New Orleans, LA, Feb., 1986.

T.H. Barrows, D.M. Grussing, and M.A. Havens, "Comparison of Tensile and Knotted Strength Retention of Synthetic Absorbable Sutures *In Vivo*", *Trans. Soc. Biomater.*, **8**, 143 (1985).

T.H. Barrows, S.J. Gibson, and J.D. Johnson, "Poly(ester-amides): *In Vivo* Analysis of Degradation and Metabolism using Radiolabeled Polymers", *Trans. Soc. Biomater.*, **7**, 210 (1984).

T.H. Barrows, D.M. Grussing, and D.W. Hegdahl, "Poly(ester-amides): A New Class of Synthetic Absorbable Polymers", *Trans. Soc. Biomater.*, **6**, 109 (1983).

T.H. Barrows, P.R. Farina, R.L. Chrzanowski, *et al.*, "Studies on Models for Tetrahydrofolic Acid: Reactions and Mechanisms of Tetrahydroquinoxaline Derivatives at the Formaldehyde Level of Oxidation", *J. Amer. Chem. Soc.*, **98**, 3678 (1976).

T.H. Barrows, "Studies on Models for Tetrahydrofolic Acid", Ph.D. Thesis, Department of Chemistry, The Pennsylvania State University, 1974.

S.J. Benkovic, T.H. Barrows, and P.R. Farina, "Studies of Models for Tetrahydrofolic Acid: Reactions of Amines with Formamidinium Tetrahydroquinoxaline Analogs", *J. Amer. Chem. Soc.*, **95**, 8414 (1973).

#### INVITED LECTURES:

"R&D Start-up Ventures", Panel Discussion, Goizueta Business School, Emory University, Atlanta, GA, April 1, 2004.

"Biotech Product Development", Seminar, Emory-Georgia Tech Dept. of Biomedical Engineering, Atlanta, GA, February 24, 2004.

"Bioabsorbable Hydrogel Tissue Sealants", Seminar, Cornell University, Ithaca, NY, November 18, 1997.

"Bioabsorbable Tissue Sealants", Clemson University Medical Textiles and Biomedical Polymers and Materials Conference, Greenville, SC, September 11-12, 1996.

"Trends in the Synthesis of Bioabsorbable Polymers". This lecture, delivered at the following locations, has been revised and updated with each presentation to cover recent developments.

Technical Workshop Number 14, The Society for Biomaterials 21<sup>st</sup> Annual Meeting, San Francisco, CA, March 18, 1995.

Clemson University Medical Textiles and Biomedical Polymers and Materials Conference, Greenville, SC, September 6-7, 1995.

Biomaterials & Medical Devices for Human Body Repair Lecture Series, Cornell University, Ithaca, NY, April 5, 1994.

Biodegradable Implant Materials Workshop, 10<sup>th</sup> European Conference on Biomaterials, Davos, Switzerland, September 8-11, 1993.